REMARKS

Claims 1-29, 31 and 35-82 were pending and claims 31, 35 and 80-82 were under consideration in the application. Claims 1-29, 31 and 36-79, withdrawn from consideration as directed to non-elected inventions, have been canceled without prejudice. Claims 31 and 80 have been amended. New claims 88-90 have been added, support for which can be found throughout the specification and claims as originally filed.

No new matter has been added.

Withdrawn Rejections

Applicants note with the appreciation the withdrawal of rejections under 35 U.S.C. § 112, first paragraph (written description), 35 U.S.C. § 112, second paragraph, and 35 U.S.C. § 102.

Rejection under 35 U.S.C. § 101

Claims 31, 35 and 80-82 remain rejected under 35 U.S.C. § 101 because the claimed invention is allegedly not supported by a specific, substantial and credible asserted utility or a well established utility. The Office alleges that the arguments presented by Applicants in response to the previous Office Action, although considered, were not deemed persuasive. Applicants respectfully disagree.

The Office further states that:

> [n]ot knowing the natural ligand or associated disease state will not allow the artisan to identify the specific or substantial utility of the claimed invention. Without knowing the function or any associated disease states of the protein or its encoding polynucleotide, then the production of antibodies, the identification of ligands, tissue localization, etc, will also not be useful. In other words, if the function of the protein is not known, then its is not understood how the artisan would utilize the antibodies, ligands, etc.

(Office Action, page 3).

The specification recites that the claimed receptor is a GPCR and is useful in the treatment and diagnosis of mental diseases/disorders including schizophrenia, depression, anxiety, Parkinson's disease, and Alzheimer's. Therefore, Applicants have set forth specific, substantial and credible utilities exist for the claimed receptors.

Utility Examination Guidelines

The Utility Examination Guidelines (the "Guidelines") require that a claimed invention have a specific, substantial and credible asserted utility, or, alternatively a well-established utility. Applicants have asserted that the claimed polypeptides are useful, *inter alia*, to generate antibodies specific for the claimed polypeptides. The utilities asserted are art-established: those skilled in the art would readily acknowledge that the claimed polypeptides are useful within the meaning of 35 U.S.C. § 101. As Applicants have asserted utilities that are specific, substantial and credible, and well established, the Utility Requirement has been satisfied. Applicants therefore respectfully request the withdrawal of the rejection under 35 U.S.C. § 101.

Under the Guidelines, Office personnel are instructed to review the specification and claims of the application to determine if a specific and substantial utility that is credible is present. The Guidelines note that the specific and substantial requirement "excludes 'throw-away', insubstantial,' or 'nonspecific' utilities, such as the use of a complex invention as landfill." The Guidelines go on to note that an Examiner's "*prima facie* showing ***must*** establish that it is more likely than not that a person of ordinary skill in the art would not consider that any utility asserted by the applicant would be specific and substantial." "If the applicant has asserted that the claimed invention is useful for any particular practical purpose (*i.e.*, it has a 'specific and substantial utility') and the assertion would be considered credible by a person of ordinary skill in the art, do ***not*** impose a rejection based on lack of utility." (Guidelines, emphasis added).

Preliminarily, Applicants remind the Office that specific and substantial utilities have been provided for the claimed polypeptides. The asserted utilities are credible to one of skill in the art. The Office has failed to provide any evidence that "it is more

likely than not that a person of ordinary skill in the art would not consider that any utility asserted by the applicant would be specific and substantial."

It appears that the Examiner's assertion that the claimed invention lacks utility may have been based upon the often-repeated examples of "throwaway" utilities, including the use of a genetically modified mouse as snake food or of the use of uncharacterized compositions as "landfill" or as shampoo ingredients. Such assertions focus on the non-specificity of such uses. For example, anything that a snake could arguably fit within its mouth could serve as food for the snake. Likewise, anything that could fit in a landfill could be a landfill component. Virtually any substance that can be dissolved in a shampoo could be used a shampoo ingredient. An important issue raised by the fact that any substance could be so used is that the substance may be wholly inappropriate for the asserted utility. In the context of a shampoo ingredient, the added substance may be highly caustic and cause serious burns to the skin. This scenario supports the logical conclusion that such a substance should be appropriate for the utility asserted. Further, to be "appropriate for use", the substance cannot be uncharacterized. Without characterization one cannot determine whether the substance is appropriate for the asserted utility.

The use of such uncharacterized substances for purposes of dubious worth stands in sharp contrast to the present invention. The claimed polypeptide was shown to be a GPCR through several rounds of analysis. Applicants also note that expression profiles of the claimed GPCR localize expression to the cerebellum, with a lower but significant expression in cerebrum. Such expression patterns support a role of the claimed polypeptide in a mental disorder such as schizophrenia.

It is clear therefore the claimed polypeptide is neither the equivalent of the uncharacterized complex invention used as "landfill" nor of a caustic substance used in a shampoo.

The Examiner compares the claimed invention to, *inter alia*, a "molecular weight marker" and asserts that molecular weight markers do not have utility under 35 U.S.C. § 101. Notwithstanding the Office's arguments regarding molecular weight markers, *inter*

alia, Applicants assume, however, that the Office recognizes that objects including molecular weight markers and calibration standards are patentable. Indeed, upon a cursory review of patents listed on the PTO's website, Applicants found numerous patents issued with claims directed to, *inter alia*, calibration standards. For example, United States Patent 6,646,737, issued November 11, 2003, claims a calibration standard. Similarly, United States Patents 6,356,069 and 6,174,728 also claim calibration standards.

The Office further cites *Brenner v. Manson* in asserting that the presently claimed invention lacks utility. Applicants respectfully assert that the Office has mischaracterized the *Brenner* decision. Applicants first note that the pending claims are not directed to processes but instead to compositions. The Office apparently failed to consider the entirety of the first sentence cited from *Brenner*. The sentence in its entirety states "Until the process claim has been reduced to production of a product shown to be useful, the metes and bounds of that monopoly are not capable of precise delineation." The equivalent of the "product" discussed in *Brenner* is the claimed polypeptide. As discussed in length above, many utilities have been asserted for the claimed polypeptides. None of the asserted utilities are incredible or have dubious worth.

Although Applicants assert that specific and substantial utilities that are credible have been provided for the claimed invention, Applicants also note that the Utility requirement may also be satisfied by an "Art Established Utility" which means that "a person of ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention . . . and the utility is specific, substantial and credible." (M.P.E.P. §2107). Well-established, art established utilities exist for the claimed polypeptides of the present invention.

The Office has failed to provide any evidence, less still a preponderance of the evidence, to cast doubt upon any of the asserted utilities. The Office has also failed to provide any evidence that the asserted utilities are "throwaway utilities" or that the claimed polypeptides are inappropriate or unsuited for the several asserted utilities. Finally, even assuming *arguendo* that the asserted utilities are not specific or substantial,

the art established utilities for the claimed polypeptides satisfy the Utility requirement of § 101.

In view of the foregoing, Applicants respectfully request that the rejection under 35 U.S.C. § 101 be withdrawn upon reconsideration.

Rejections under 35 U.S.C. § 112, first paragraph

Claims 31, 35 and 80-82 remain rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to adequately teach how to use the instant invention. According to the Office, "since the claimed invention is not supported by either a specific, substantial, and credible asserted utility, or a well established utility, one skilled in the art clearly would not know how to use the claimed invention." (July 29, 2003 Office Action). Applicants do not agree.

As discussed above, the present invention ***is*** supported by a specific, substantial, and credible asserted utility as well as a well-established utility. One skilled in the art having read the present application would be able to make and use the claimed invention.

Claims 80-82 remain rejected under 35 U.S.C. § 112, first paragraph, for the reasons of record set forth on pages 3-4 of the July 29, 2003 Office Action.[1] The Examiner alleges that the "claims do not recite a functional limitation" and "it is not predictable to one of ordinary skill in the art how to make a functional sodium channel which is less than 100% identical to that if SEQ ID NO:2. ... In summary, the breadth of the claims is excessive in regard to Applicants claiming all proteins which are at least 95% identical to SEQ ID NO:2". (Office Action, page 4). Applicants do not agree.

Preliminarily, Applicants note that new claims 88-90 have been added. New claim 88 recites that the polypeptide has an amino acid sequence which is at least 99% homologous to SEQ ID NO:2.

[1] Pages 3-4 of the July 29, 2003 Office Action state that the specification ***is*** enabling for the protein of SEQ ID NO:2 but "does not reasonably provide enablement for proteins which are at least 60-95% identical to SEQ ID NO:2, or which hybridize to SEQ ID NO:1."

Claim 80, as amended, and new claims 89 and 90 recite functional limitations. Therefore, as set forth in the Specifically July 29, 2003 Office Action, Applicants assert that claims 80-82 and new claims 88-90 are free of the present rejection.

The Office also alleges that undue experimentation would be required to practice the invention as claimed. Applicants do not agree. Any experimentation that may be required to practice the claimed invention is not undue. Even though a large amount of experimentation may be required, the types of experiments are routine for the skilled artisan. "The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed." (M.P.E.P. § 2164.06). Even complex or time-consuming experiments are not necessarily undue. "[t]he fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation." (M.P.E.P. § 2164.01).

The present application provides a ***reasonable amount*** of guidance with respect to the direction in which the experimentation should proceed. The present application describes the sequences of the invention and sets forth several examples of assays to assess the functionality of the GPCRs.

In view of the foregoing, Applicants respectfully request that the rejection under 35 U.S.C. § 112, first paragraph be withdrawn.

Conclusion

Applicants believe the claims are in condition for allowance. An early Notice of Allowance is therefore earnestly solicited. Applicants invite the Examiner to contact the undersigned at (215) 665-6904 to clarify any unresolved issues raised by this response.

Respectfully submitted,

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